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Mark B. McClellan, MD, PhD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Land
Rockville, MD 20857

Dear Commissioner McClellan:

Physicians for Reproductive Choice and Health® (PRCH) urges you to approve the application of Women's Capital Corporation and Barr Laboratories to move a dedicated emergency contraceptive pill from prescriptive to over-the-counter (OTC) status. PRCH strongly supports the overwhelming evidence-based and public health imperative for over-the-counter access to emergency contraceptive pills (ECPs).

We understand that you have requested an additional 90 days to review Barr's application, and are deeply concerned that this is simply a delay tactic.

The FDA's own advisory committees reviewed the scientific evidence in December and voted overwhelmingly (23-4) in favor of making the product available without prescription.

By the FDA's own criteria, and in the wake of overwhelming scientific data supporting the efficacy and safety of ECPs, prescription-only status is medically unjustified and indefensible. When we consider each of the four FDA criteria for OTC status, ECPs meet them all:

- *Treatment must be self-diagnosable.* No one is more likely to diagnose contraceptive failure (or failure to use contraception) than the woman herself.
- *Treatment must be effective when self-administered.* Correct administration of ECPs relies only on how much time has elapsed since intercourse. All patients receive the same dose of ECPs, and any drug interactions would be harmless and unlikely to seriously affect efficacy.
- *Treatment must be safe when self-administered.* ECPs are nontoxic to women, as well as to a developing fetus in case of established pregnancy. The product has a low risk of abuse and few, minor side-effects.
- *Labeling must be clear for self-administration.* As demonstrated by research, ECP instructions are simple, clear, comprehensive, and easy-to-follow.

Professional and public support of the OTC switch is obvious, as more than 70 organizations are signatories to the 2001 Citizen's Petition for Status Change for Emergency Contraception. Among the numerous medical and public health organizations supporting the switch are: the American Medical Association, the

American College of Obstetricians and Gynecologists, the Association of Reproductive Health Professionals, the American Academy of Pediatrics, the American Medical Women's Association, the American Nurses Association, the National Association of Nurse Practitioners in Women's Health, the American Public Health Association, Planned Parenthood Federation of America, the Black Women's Health Imperative, Advocates for Youth, and the American Pharmaceutical Association as well as PRCH.

Despite being the wealthiest nation in the world, the United States has the highest rate of unintended pregnancy among industrialized nations. As of 1994, nearly half – 49 percent – of all pregnancies in America were unintended, and more than half – 54 percent – of those ended in abortion. Among women aged 15-44, 28 percent have had an unplanned birth, and 30 percent have had an abortion. These numbers are problematic, as unintended pregnancy is associated with both high maternal morbidity and economic costs. Fortunately, unintended pregnancies are largely preventable, and increasing use of effective contraception has led to an overall decline of unintended pregnancies since 1987. Health experts estimate that widespread use of emergency contraception could prevent as many as 1.7 million additional unintended pregnancies each year.

The majority of American women use contraception. Of the 60 million women aged 15-44, 64 percent practice contraception. Nearly all – ninety-three percent – of women aged 18-44 who are sexually-active, non-sterile, and not attempting to conceive use a form of contraception. Most of these women – 61 percent – use reversible contraceptives like condoms or the pill, and the remaining women rely on male or female sterilization. Overall, women use their contraception responsibly and effectively, as actual-use studies show success rates from 88 to 99.6 percent for reversible methods, and more than 99 percent for non-reversible methods of contraception.

Contraception, regrettably, is neither universally utilized nor fail-proof. Unintended pregnancies occur in both the small percentage of women who don't use contraception, and in women for whom contraception fails, emphasizing the need for the broader availability of ECPs.

There was concern expressed by a few members of the two Committees who reviewed this application about the affect of OTC status on adolescents. At least six major scientific studies have focused specifically on adolescents and ECPs. The conclusions uniformly report that adolescents will use the product correctly and infrequently. Findings from a University of Pittsburgh study indicated that adolescent girls given an advanced supply of ECPs were more likely to use it when needed, and reported fewer unintended pregnancies and sexually transmitted diseases. Other studies confirmed that teens' use of regular contraceptives like condoms do not decline with ECP use, and a study of young women in Britain found that using ECPs following a pregnancy scare may actually make women *more* likely to use an effective, ongoing contraceptive method. Facilitating adolescents' access to ECPs is particularly important, as teenagers often have significant trouble gaining access to reproductive health information and care. Research shows that in settings as diverse as Scotland and Hong Kong, adolescents know more about emergency contraception and use it more frequently than in the United States.

Medical decisions should be rooted firmly in scientific evidence. Research on emergency contraception – including numerous randomized trials, data on actual use, and label-comprehension studies – has revealed that prescription-only status of ECPs is both gratuitous and harmful. Prolific research on ECPs documents their safety, efficacy, and ease-of-use, along with the economic benefits of OTC status for individuals, institutions, and public systems. The Institute of Medicine

stated that establishing "evidence-based" medicine should be at the forefront of modern medicine's agenda, and has advocated in favor of aggressive efforts to reduce unintended pregnancy rates in America. The FDA can bring the medical community one step closer to reaching both goals by acknowledging the overwhelming evidence and granting OTC status to ECPs.

Prescription-only status of ECPs is deeply frustrating for both patients and healthcare providers. A majority of my colleagues and our professional organizations share these sentiments. The American College of Obstetricians and Gynecologists has officially stated that ECPs "can meet the FDA criteria for OTC availability," and that "substantial barriers exist to women obtaining this fallback contraceptive method that must be used within 72 hours after unprotected intercourse." Similarly, the American Medical Association declares that it will work to improve access to ECPs while promising to "support and monitor the application process of manufacturers filing for OTC approval of ECPs with the Food and Drug Administration."

Condoms and spermicides are widely available over-the-counter. As a product that could drastically reduce the rate of unintended pregnancy, ECPs should share their over-the-counter status. Simply stated, emergency contraception is effective and safe, and it is indefensible to not have it available over-the-counter. PRCH urges you to follow your own criteria in the light of overwhelming evidence and grant this application.

Sincerely,

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